PERIODONTAL SCREENING

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PERIODONTAL SCREENING

1. Background and Rationale

This clinical periodontal examination will provide a basis for categorizing patients with respect to their level of gingival inflammation and periodontal disease status. There is increasing evidence that periodontal disease, which is a gram negative, chronic infection, acts as one of the principal sources of chronic inflammation in older adult populations. Furthermore, this chronic inflammatory state leads to an elevation in local (gingival crevicular fluid) and systemic (serum) levels of cytokines and other pro-inflammatory mediators. Mechanisms have been proposed that relate chronic elevation in pro-inflammatory mediators to a number of systemic consequences. To date, research has found that periodontal disease elevates the risk of cardiovascular disease, Type 2 diabetes onset, poor glycemic control in established diabetics, and pre-term births in expectant mothers.

Evidence exists that changes in body composition are also related to levels of pro-inflammatory mediators. This study will examine the possibility that periodontal disease acts as a source of pro-inflammatory mediators leading directly to changes in body composition via altered metabolism and indirectly via induction of systemic conditions that alter body composition (e.g., diabetes, heart disease). Specifically this study will test the hypotheses that:

- 1) there will be an association between prevalent (clinic visit 2) measures of periodontal disease and prevalent measures of body composition (lean mass), strength, and function;
- 2) there will be an association between prevalent (clinic visit 2) measures of periodontal disease and incident changes in body composition (lean mass), strength, and function (measured at subsequent Health ABC clinic visits);
- 3) Periodontal disease will be associated with greater incidence of cardiovascular disease-based morbidity which will lead to loss of lean muscle mass; and
- 4) Periodontal disease will be associated with greater incidence of Type 2 diabetes also leading to changes in body mass.

2. Equipment and Supplies

2.1 Instruments

Dental Mirror

UNC-15 Probe

Tongue Blade

- 3 Universal Curettes (double-ended i.e. Columbia 4R/4L)
- 3 Cotton Forceps

2.2 Disposables and Storage

For Gingival Crevicular Fluid (GCF) Only

Cotton Rolls

2 Sets of Perio Paper

4 GCF Cryovials with Colored Tops Designating the Mediator

4 Sterile Aluminum Foil Strips

Perio Paper Holder

Dewer's Flask with Liquid Nitrogen

Calibrated Periotron (Harco@)

For Microbial Sampling Only

5 Conical Bottom Tubes (2.0ml) with:

- 0. l ml Sterile TE Buffer Before Sample
- 0.1ml Sterile 0.5M NaOH Buffer After Sample Cotton Rolls

2.3 Computer Supplies

Two sets of 3 1/2" floppy disks (one for backup and one for shipping)

2.4 Additional Equipment

Hamilton Syringe (for Periotron Calibration) 100ml Micropipette with Sterile Tip

2.5 Forms

Periodontal Eligibility Assessment (in Year 2 Clinic Visit Workbook) Periodontal Examination (to be used only if voice-recognition software fails) BANA Test Form

Dental History (portion of Year 2 Questionnaire)

Quality Control Procedure Checklist Assay Recording (GCF Cards, Accession Number Log, etc.) Oral Health Examination Report Dental Examination Addendum Form

3. Maintenance of Periotron (if GCF collection is being performed)

3.1 Calibration and general information

Detailed documentation of calibrations of the Periotron must be kept in the study notebook. Calibration of the Periotron involves obtaining readings on a series of measured amounts of fluids. There are two different procedures used for calibration. A comprehensive calibration is performed at the beginning of the study and at any point during the study when an interim calibration is out of range. A simpler, three point calibration procedure is completed each week before using the Periotron.

3.1.1 Instructions for calibrating the Periotron

3.1.2 Comprehensive calibration

The purpose of a comprehensive calibration is to establish the relationship between the Periotron readings and the standard volumes of water. The steps for a comprehensive calibration are as follows:

- Distilled Water is used for calibrating. Operators should always wear latex gloves. A small amount of water kept in a cryovial is easier to access for measurement. The Hamilton Microliter Syringe is used for measuring the water. It is very important that the instructions for use of the Hamilton Microliter Syringe be followed carefully.
- 2. Initially, turn on the Periotron and allow it to warm up for at least 10 minutes. Open a pack of Periopapers and secure it to the Periopaper holder. Clean the sensors with an alcohol wipe and dry with cotton gauze.

(NEVER TOUCH THE WHITE PAPER STRIP WITH YOUR GLOVED FINGERS)

3. Place a dry Periopaper on the lower sensor aligning the edge of the sensor with the black margin on the strip. Close the upper sensor on the dry strip and move

hands away from the sensor. Adjust the Zero Adjustment knob until "60" appears on the digital readout.

- 4. Repeat the test for "zero" two additional times using clean, dry Periopaper each time. A slight drift of values after adjusting the zero knob is acceptable up to a reading of "2." A reading producing a blank line is not acceptable.
- 5. Using locking cotton pliers, remove one Periopaper from the holder; and, being careful not to let the white strip contact another surface, place the cotton pliers on a flat surface. Set the Hamilton Microliter Syringe to the first volume indicated on the comprehensive calibration document form (see form below). Load the pipette with this indicated amount of distilled water from the vial and empty the water from the pipette onto the Periopaper. It is best to empty the water onto the lower half of the Periopaper close to the tip.
- 6. Without delay, place the Periopaper on the sensor of the Periotron being careful to line up the edge of the black mark on the strip with the edge of the sensor (do not have the sensor touching the black line on the strip). The periopaper is "positive sensitive" so each operator should always place Periopaper on the sensor in the same position for each Periotron. After placing the Periopaper on the sensor, always move your hand away from the instrument. Wait approximately 15 seconds until the "11" lights up on the Periotron indicating that the reading is final. Record this reading on the calibration form.
- 7. After each reading, the sensors of the Periotron unit should be wiped with a prepackaged, sterile alcohol wipe and allowed to dry for 15 seconds; or you may dry the alcohol with a gauze pad.
- 8. Procedures 5 through 7 should be repeated for each volume indicated on the calibration form. Each volume will be repeated three times before the calibration is completed. The volumes are given on the calibration form in a randomized order. Calibration forms will be provided.
- 9. A copy of the calibration documentation form is kept in the Investigator's study notebook.

SEE NEXT PAGE (FORM)

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COMPREHENSIVE PERIOTRON CALIBRATION

Protocol #: Site # Date of Calibration: Periotron Serial #: Person Calibrating:	
Did the Periotron warm up for at least 10 minutes?	☐ Yes ☐ No
Was the Periotron adjusted to "zero" three times? \Box	Yes No
Randomized Volumes of Distilled Water*	Periotron Reading
microliters, complete calibration in the order given	. ononon nodemig
0.05	
0.05	
0.05	
0.8	
0.8	

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0.1	
0.1	

^{*}Water is measured in microliters with a Hamilton Microliter Syringe

3.1.3 Weekly Interim Calibration

The interim calibration is a three-point calibration intended to validate sampling values to the comprehensive calibration. This procedure should be completed weekly before the Periotron is used. Repeat the steps given previously recording three readings each for 0.1 microliters, 0.4 microliters, and 0.7 microliters of water. Record the three readings on the interim calibration documentation form. A copy of the calibration should be kept in the Investigator's notebook on site (see form on next page).

Compare the interim data to the comprehensive calibration ranges for each individual Periotron. In the event that the weekly calibration values deviate more than the range provided, complete a comprehensive calibration. It is very important that the same individual complete the comprehensive calibration and the interim calibrations.

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2. Interim Periotron Calibration Form

Protocol #:	DARIC			
Site: _			:	
Date of Calibration:				
Periotron Serial #:				
Person Calibrating:			ļ	
	up for at least 10 minutes? (circle one ded to "zero" three times? (circle one		No No	
Randomized Volume	s of Distilled Water*			Periotron Reading
(in microliters, comp	lete calibration in the order given)			
	0.1			
	0.1			
	0.1			
	0.4			
	0.4			
	0.4			
	0.7			
	0.7			
	0.7			
	1.0			
	1.0			
	1.0			
*Water is measured	in microliters with a Hamilton Microlite	er Syringe	,	
	n reading for each of the above volum aprehensive calibration range provided			

3.2 General Periotron 6000 information

- Keep hands away from the sensors during measurement.
- Never close the Periotron jaws on anything thicker than paper.
- Turn the power switch off if you experience voltage fluctuations or electrical storms.
- When not in use, leave a Periopaper strip between the closed jaws.

4. Safety issues and exclusions

Participants who are determined to be at risk were they to have a dental examination without the use of an antibiotic immediately prior to, and following a dental examination will be excluded from the dental exam. Exclusions for the dental exam will be determined during screening. See section 5.1 below for detailed instructions for exclusion determination.

5. Screening and scheduling

5.1 Screening

5.1.1 General screening instructions

The periodontal exam eligibility assessment is administered during the year 2 clinic visit. The purpose of the Periodontal Exam Eligibility Assessment form is to determine whether an Health ABC participant is eligible for the Periodontal Component of the exam. This includes identifying individuals who might be placed at risk were they to have a dental examination without the use of an antibiotic immediately prior to, and following a dental exam. These exclusion criteria are based on the American Heart Association guidelines for the identification of individuals at higher than acceptable risk of contracting endocarditis without the prophylactic use of antibiotics prior to any dental examination or procedure.

The DENTAL SCREENING questions begin by determining whether the person has any teeth on which to observe the presence of periodontal disease or whether the person would be placed at risk if a dental examination were performed without

coverage by an antibiotic. As soon as an exclusion criterion is identified, check the appropriate response category and skip to item 11. Select the NO category (the person meets an exclusion criterion), and read the appropriate statement which explains to the person why it may not be useful or safe for participation in this portion of the study.

5.1.2 Detailed screening instructions

Below are detailed instructions for filling out the Periodontal Exam Eligibility Assessment form (Appendix 1):

Instructions for completing the form above:

- l.a Do you have ANY of your natural teeth? Natural teeth may be defined as the teeth you got as you were growing up. A response of YES means the person has at least one natural tooth visible above the gum line. If YES, continue with item 2. A response of NO means there are no visible teeth, regardless of whether the roots are present, or the person is unsure as to whether there are any visible natural teeth. Ask the participant how many years ago they lost their last tooth. Continue with Item l.b
- l.b Do you have any dental implants? Dental implants may be defined as replacement teeth that are surgically implanted (placed) in the mouth by a dentist. It is very unlikely that a person with dental implants will be unaware of having them, as these teeth are screwed into the jaw bone, a procedure which requires lengthy surgery and recovery. Persons who have no natural teeth, but have dental implants, can be evaluated for periodontal disease, and therefore are NOT excluded. If a person has dental implants, select YES and continue with Item 2. If the person has no natural teeth and no dental implants, select NO. This person is not eligible to have the full periodontal examination. Go to Item 11, select NO, and read the statement below the NO checkbox.
 - "Thank you for your responses. This next measurement includes a simple examination of your mouth."
- 2. Has a dentist or doctor ever told you that you need to take antibiotics before every dental visit? A response of YES means that the person has previously been told (time frame unspecified) by their dentist or a medical doctor that they should routinely take an antibiotic before any kind of dental exam or procedure. If YES, select YES. Ask why they were told to take an antibiotic, and record the reason in the space provided. Note that it is not necessary that the reason for

taking the antibiotic is included in the AHA guidelines. A positive response, for whatever reason, means the person is not eligible to have a periodontal exam. Go to Item 11, select NO, and read the statement below the NO checkbox.

"Thank you for your responses. This next measurement includes a simple examination of your mouth."

3. Has a doctor ever told you that you have any of the following? Read the introductory portion of the question, stressing physician diagnosis ("has a doctor") and the life time applicability of the question ("ever told you"), and then read each medical condition until the participant reports a positive condition or you complete the list. Check the appropriate response. Participants who don't know if they have the condition are not excluded. Definitions of the medical terms are printed in the table at the end of the instructions and may be read to participants if they are unclear as to whether they have the condition (see Appendix 2). A positive response (YES) requires the person to have been given the diagnosis by a physician. If there is a positive response, select YES. No further questions about exclusion criteria need to be administered. Go to Item 11, select NO, and read the statement below the NO checkbox.

"Thank you for your responses. This next measurement includes a simple examination of your mouth."

- 4. Are you taking prednisone or an immunosuppressive medication? Follow the above procedures.
- 5. Do you have a cardiac pacemaker? Record the response. When the response is NO or UNKNOWN, continue with the next question. When the response is positive, select YES, and go to Item 11. Select NO. Read the statement below the NO checkbox.
- 6. Do you have a surgically implanted heart valve, artificial joint, shunt or other body part? Follow the above procedures.
- 7. Have you had major surgery, radiation, or chemotherapy for cancer within the last 2 months? The object of the question is to identify persons who have been treated for cancer within the past 2 months who might also need a prophylactic antibiotic for a dental exam or procedure. For example, persons who have had minor surgery to remove a skin cancer without adjuvant radiation or chemotherapy need not be excluded from the dental exam. However, all

situations which involve questionable eligibility should be discussed and resolved with the clinic physician before telling the person that they are or are not eligible to participate.

- 8. Are you on kidney dialysis? Follow the above procedures.
- 9. Have you had a heart, kidney or other organ transplant? Follow the above procedures.
- 10. Did you ever take Fen Phen to lose weight?
 - If the participant says they took Fen Phen or another diet pill and they don't remember the name, the participant is excluded. Follow the above procedures.
- 11. Is the participant eligible for the periodontal assessment? In general, as soon as a participant meets an exclusion criterion, no more exclusion conditions are filled out. Select NO, and read the statement below the NO checkbox. When no exclusion criteria are noted during the interview, select YES, and read the recruitment statement, and answer any questions.

5.2 Explanation of components of the dental exam

This portion of the study includes a simple examination of your mouth to see if there are any gum disease, cavities, or spaces between your teeth and gums. We will also collect a little plaque (tartar) and pick up some fluid from around your teeth Most people find these procedures to be quite comfortable.

5.3 Explanation of results reports

The usual procedure in Health ABC is to send your doctor a copy of your results reports. If you would like us to send your dentist a copy of the dental exam report, please bring their name and address with you when you come for your appointment.

6. Participant and exam room preparation

Ask questions about the dental history <u>prior to</u> the dental examination. These questions begin on page 23 of the Year 2 Questionnaire and include Questions 42 through 54. This is done because we do not want answers to reflect exam findings. If the participant requests to clean their teeth prior to the exam, give them a cup and they

may rinse with water only. The participant should not brush their teeth or use mouthwash immediately prior to the exam. They may brush or use mouthwash after the exam.

6.1 Clinic preparation

6.1.1 Computer set-up

Each study center will have an IBM compatible computer. Data entry programs necessary to collect data from the clinical exam are pre-installed on the computer.

6.1.2 Instruments and supplies

In preparation for the clinical exam and sample collection the following instruments and supplies should be set up in the operatory:

Instrument Kits

Each study center will be provided with 8 instrument trays. One will be used for each participant and should be sterilized and set up in the operatory prior to the participant arrival. These kits include the following instruments:

- Dental Mirror
- UNC-15 Periodontal Probe
- · Tongue blade
- 14R/4L Curettes
- 2 Cotton Forceps

Supplies and Equipment On Site

Each study center that does the full GCF examination will have the following supplies and equipment made available to them and kept at the study center. Each of the following will need to be used at each participants visit:

- Periotron (Harco)
- Dewars Flask
- Liquid Nitrogen
- Periopaper Holder (2)
- Instrument Kits (8)

- Autoclave
- Self-sealing autoclave bags
- 0.5M NaOH in bottle with dispenser
- cotton rolls
- gauze 2x2
- holding rack for sample vials

Note: The Hamilton Syringe will be used weekly for Periotron calibration

Participant Kits

Each study center that does GCF collection will be sent one kit per participant. Each kit will include:

- GCF Vials (4)
- Conical Bottom Tubes (4) (sterile w/ TE buffer)
- Sterile Aluminum Foil Strips (4)(fingerprint-free)
- Periopaper (1 set)
- Sample requisition form to be completed

Sample Requisition Forms

Each form will have a preprinted participant number with initials. One form will be in each participant sample kit and needs to be filled out during the visit. It includes participant information, sample information, and preprinted accession numbers corresponding to each sample to be collected. Vials will be pre-labeled. Each vial (and each sample) has a unique number according to the following system:

```
Digits 1 and 2 = Study Designation (two letters)

Digits 3 through 9 = Participant ID number (one letter, 6 numbers)

Digit 10 = Sample Type -

1 = GCF
2 = Plaque
```

Digit 11 and 12 = Sample Number

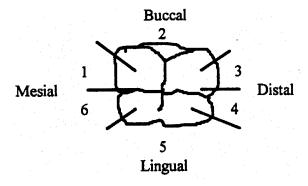
```
1-16 = GCF (four samples placed in each of four vials)
17-20 = Plaque (four samples placed in each of four vials)
```

For example the number: ABP126423217 would designate the following sample: The Health ABC study ("AB" in the first two digits), participant number P126423 (from

Pittsburgh site), a plaque sample ("2" in the tenth digit), and a sample number "17" (the first plaque sample)

6.2 Quadrant - Tooth - Site (QTS) System

The new chart utilizes the QTS System for site nomenclature. QTS (Quadrant - Tooth - Site) utilizes a 3-digit code for charting purposes. The first digit of this code corresponds to the quadrant with the UR = #1) UL = #2, LL = #3 and LR = #4. The second digit in this code corresponds to the tooth. Teeth are numbered 1-8 beginning at the midline and counting distally. The third digit corresponds to site designation and is numbered 1-6 beginning at the mesio-buccal site of each tooth, numbering the sites distally and peripherally around each tooth, and ending with site #6 at the mesio-lingual site.



7. Detailed measurement procedures

7.1 Instructions for filling out the Dental History Form

Use standard Health ABC interviewing techniques to administer the Dental History exam. The Dental History form is administered to all Health ABC participants, regardless of whether they are eligible for the dental examination. The form documents aspects of the participant's dental status which may be related to a history of chronic inflammation. It includes questions on the cause(s) of tooth loss, loose teeth, false teeth, root canal(s), dental implant(s), frequency of teeth brushing and flossing, and the use of dental care.

7.1.1 Detailed instructions for each item

Below are instructions for completing the Dental History form (pages 23 through 26 of the Year 2 Questionnaire / Appendix 3):

- 42. "How would you rate your overall oral health (teeth, gums, inside of mouth)?" The choices are excellent, good, fair, and poor. If the participant does know, check DON'T KNOW.
- 43. "How often do you brush your teeth in an average day?" Read the question and select the response category which corresponds to the person's answer.
- 44. "How often do you use dental floss in an average week?" Read the question and select the response category which corresponds to the person's answer.
- 45. "How often do you go to your dentist for a check-up?" Read the question and select the response category which corresponds to the person's answer. "Dentist" can be defined in terms of an individual practitioner or a clinical setting (facility) in which dentistry is practiced.
- 46. "Have you ever been told by a dentist or periodontist that you have gum (periodontal) disease?" If the participant answers YES ask: "When were you last treated for gum disease?" and select the response category which corresponds to the person's answer.
- 47. "Have you lost any teeth because of gum disease?" Read the introductory phrase. Record a response of YES, NO, or DON'T KNOW. In general, the loss of any one tooth will be due to just one cause. Causes other than gum disease should be listed as "NO." There may be exceptions. For example, when a participant reports both the loss of a natural tooth (teeth) because it rotted out and severe gum disease prior to the loss of that tooth, it may not be possible to determine which condition lead to the tooth's removal. In that case, you would select YES for gum disease. If the participant answers YES ask: "How old were you when you first lost teeth because of gum disease?" Record answer in boxes provided.
- 48. "Do you limit the kinds or amounts of food you eat because of problems with your teeth or dentures?" The interviewer should read the response options, which are: ALWAYS, OFTEN, SOMETIMES, SELDOM, AND NEVER. Record participant's response.

- 49. "Do you have trouble biting or chewing any kinds of food, such as firm meat or apples?" Read response options: ALWAYS, OFTEN, SOMETIMES, SELDOM, AND NEVER. Record participant's response.
- 50. "Does the amount of saliva in your mouth seem to be . . . ?" Read response options: TOO LITTLE, TOO MUCH, DON'T NOTICE. Records participant's response.
- 51. "Does your mouth feel dry when eating?" Record participant's response.
- 52. "During the past 3 months, how much pain have your gums or teeth caused you?" Read response options: A GREAT DEAL, SOME PAIN, A LITTLE PAIN, NO PAIN AT ALL. Record participant's response.
- 53. "During the past 3 months, how often have you had trouble chewing food or eating because of problems with your teeth or gums?" Read response options: MOST OF THE TIME, SOME OF THE TIME, A LITTLE OF THE TIME, NONE OF THE TIME. Record participant's response.
- 54. "During the past 3 months, how much of the time have problems with the way your teeth or gums look caused you to avoid conversation with people?" Read response options: MOST OF THE TIME, SOME OF THE TIME, A LITTLE OF THE TIME, NONE OF THE TIME. Record participant's response.

7.2 Performing the measurement

7.2.1 Clinical exam and sample collection

7.2.1.1 Initial data entry screen

Turn on computer.

Double click Voice Data Entry icon

Initial screen requires entry of Participant ID and reentry of ID for verification: The initial data entry screen (see below) has spaces to enter the participant's ID number. When the ID is entered, the cursor jumps down to the section labeled, Validate ID. The space with the original ID entry is blanked out and the ID number is entered again. If the ID numbers do not match, you must start over. Then enter visit number "2" (one digit) and Examiner ID number (two digit). Upon completion the program will take you directly to the "missing teeth" screen, where all present/missing teeth are entered and then through the rest of the exam....

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_____ Dental ARIC

ID: 000000 DATE: 00/00/90 Examiner: 000 Recorder: 000

Validate ID

Oral Lesions: 0

7.2.1.2 Soft tissue and teeth screening

<u>Soft tissue:</u> This screening is done as a service to the participant. We are looking for any suspicious lesions or conditions that should be referred to a dentist. If any such conditions are seen, an entry of "1" should be made for "Oral Lesions" on the first data entry screen. If nothing is noted, an entry of "0" is made. A "1" entry will then be noted by the computer in the Participant Summary and Recommendations Form. This screening examination is performed with a tongue blade and mirror and should cover the following areas:

- upper and lower lips, including the Vermillion border
- labial mucosa
- buccal mucosa from the maxillary vestibule to the mandibular vestibule
- palpate cheeks
- mucosa of hard and soft palate
- uvula, tonsillar pillars, mandibular retromolar pad, and posterior pharyngeal wall
- dorsal surface of tongue
- ventral surface of tongue and anterior floor of mouth

<u>Teeth:</u> The teeth screening is done in order to record gross evidence of periodontal disease. Thus, whether or not a participant is eligible for probing for attachment loss, some data will be captured about periodontal disease. In addition, obvious loose, broken, or carious teeth are reported as a service to the participant.

The examiner performs the teeth screening exam during the soft tissue exam using a tongue blade and mirror. The following abnormalities should be noted on the addendum data collection form (Appendix 6):

- Probable caries (number of teeth involved)
- Mobility (number of teeth involved)
- Root fragment (number of teeth involved)
- Furciation (ability to probe between roots of a tooth) (number of teeth involved)

7.2.1.3 Missing teeth

The first pass through the mouth is to identify missing teeth. Start in Quadrant 1, tooth 8 and proceed to tooth 1. Then move to Quadrant 2, tooth 1 and continue to tooth 8, followed by Quadrant 3, tooth 8 - 1; and then Quadrant 4, tooth 1 - 8.

When a missing tooth space is encountered, enter the quadrant and tooth number of the missing tooth. The first missing tooth is recorded in the space numbered "1" and additional teeth are entered in sequence up to 31 teeth. After you press the Page Down key, the computer will identify missing teeth on all subsequent data entry screens.

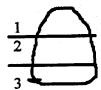
Missi	ng Teeth	
1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	17 0 0 18 0 0 19 0 0 20 0 0 21 0 0 22 0 0 23 0 0 24 0 0 25 0 0 26 0 0 27 0 0 28 0 0 29 0 0 30 0 0 31 0 0	n to Continue

7.2.1.4 Plaque score (PS)

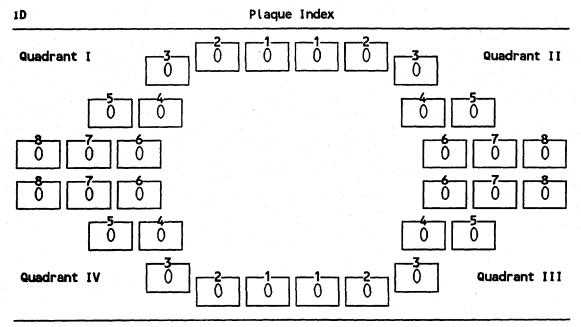
Plaque scores for the buccal surface of each tooth are determined on a 0 - 3 scale. The tooth surface to be scored should be air dried and not disclosed. The plaque score is recorded in the appropriate box for each tooth on the computer screen

0 = absence of plaque or stain of the clinical crown

- 1 = deposits covering less than one-third of the surface
- 2 = deposits covering less than 2/3 of the surface
- 3 =deposits covering more than 2/3 of the surface



Plaque scores are recorded on the buccal surfaces moving from Quadrant 1 through Quadrant 4. The computer form is shown on the next page.



Plaque

- 0 = Absence of Plaque or Stain
- 1 = Deposits covering less than 1/3 of surface
- 2 = Deposits covering less than 2/3 of surface
- 3 = Deposits covering more than 2/3 of surface

7.2.1.5 Gingival index: Loe & Silness

This is a tooth-based score. Mesiobuccal to distobuccal surfaces are examined. Periodontal probe is placed under the gingival margin at the mesiobuccal site and swept along the buccal surface to the distobuccal site and bleeding is noted.

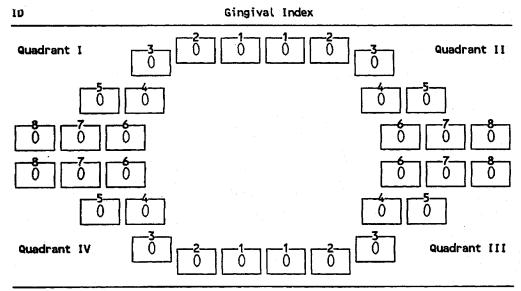
- 0 = Normal gingiva
- 1 = Mild inflammation: slight change in color, slight edema. No bleeding on probing.
- 2 = Moderate inflammation: redness, edema, and glazing. Bleeding on probing.
- 3= Severe inflammation: marked redness and edema. Ulceration. Tendency to spontaneous bleeding.

Sequence of Exam.

The sequence is the same as for caries:

Quadrant 1: teeth 8 - 1 Quadrant 2: teeth 1 - 8 Quadrant 3: teeth 8 - 1

Quadrant 4: teeth 1 - 8.



Gingival Index

- 0 = Normal gingiva.
- 1 = Mild inflammation: slight change in color, slight edema.
- No bleeding on probing.
- 2 = Moderate inflammation: redness, edema and glazing.
 - Bleeding on probing.
- 3 = Severe inflammation: marked redness and edema. Ulceration. Tendency to spontaneous bleeding.

7.2.1.6 Collection and storage of gingival crevicular fluid

This protocol describes the methods for the collection of crevicular fluid, volume quantitation, crevicular fluid storage and PGE, RIA.

Overview

Crevicular fluid is collected using Harco Periopaper prior to any probing measurements. A site (identification described below) is first isolated with cotton rolls and air dried. The periopaper strip is placed gently into the crevice and left in place until the strip is visibly dampened. The fluid volume is determined with a calibrated Harco Periotron. This volume is used to compute the final mediator concentration. Each GCF sample is assayed independently for a chosen inflammatory mediator. This enables the determination of a site-specific mediator level as well as an overall participant mean % standard error for statistical testing. Periopaper strips will be wrapped in aluminum foil, sealed in screwtop vials, catalogued and stored in liquid nitrogen.

1. Techniques for GCF Samples & Storage

The site to be sampled is identified from the data entry screen, then isolated with cotton rolls and air dried. Make sure there is not saliva pooling at the gingival margin. The examiner and the assistant wear rubber gloves when collecting samples; do not touch periopaper or aluminum foil with fingers as fingerprints cause false positives in RIA. A periopaper strip is placed into the crevice of the tooth with cotton pliers and left in place until the strip is visibly dampened, but not saturated to the orange saturation mark on the strip. The strip is gently placed until it is held by the gingival margin without attempting to push the strip down into the pocket. This is referred to as an orifice sampling method. It is then removed with pliers and measured on a calibrated Harco Periotron. The reading from the Periotron should be between 30 and 180, as readings outside this range are less reliable by linear extrapolation. If the reading is not in this range the sample should be taken again with a new strip. The Periotron reading is recorded on the sample requisition form with the corresponding OTS # (see example) and into the computer screen along with the QTS location. The filter paper strip is then placed onto a strip of aluminum foil and the foil folded over to cover the strip. Be sure to wrap each strip once by folding before placing the next strip. For this purpose use the precut aluminum foil. Always wear gloves when handling foil so as to avoid GCF contamination with fingerprints. The next filter paper strip is then placed on the aluminum foil and the foil is folded over to make sure that the filter papers do not touch. The aluminum foil strip is rolled until all four samples are taken, and then folded completely. Four strips will be placed into each of four vials for a total of 16 GCF samples. The last filter paper strip put onto the aluminum foil is, by necessity, the first strip removed. Thus, as the foil is unfolded, the samples are uncovered in the reverse order from which they were taken. As soon as four samples have been collected into the aluminum foil, the foil is placed into a 1.5 ml. screw top cryovial and placed immediately into liquid nitrogen chairside. Prostaglandins deteriorate rapidly at room temperature in the presence of oxygen, thus it is very important to get the samples into liquid nitrogen as soon as possible. The small Dewars flask containing liquid nitrogen at chairside is used for this purpose.

It is absolutely critical since more than one mediator is to be analyzed that there be only one piece of foil with the GCF strips grouped for that mediator. Thus, one vial should contain only one foil piece which has GCF strips to be analyzed for only one mediator. Since four mediators are to be analyzed there are four vials. Sampling should proceed one mediator at a time, 1 GCF from each quadrant (as shown on the computer screen). After four GCF samples are collected, the vial is put into liquid nitrogen and then four more samples are taken for the next mediator, until all 16 GCF samples have been collected. Again remember to include at least one full turn of foil between subsequent strips, otherwise they can fall together during unwrapping.

If a GCF sample is dropped, contaminated with saliva, lost or has a questionable reading, discard the sample and take another GCF sample from the same site and proceed as before.

2. Selection Criteria for Sites

The computer will automatically select the sites for sampling based on the pattern of missing teeth and implants. We do not collect plaque and GCF around implants, thus implants will be considered to be missing teeth for the purpose of site selection. Samples will be taken on sites 1 and 3 of the two most posterior teeth in each quadrant, excluding third molars. If there are no teeth in a quadrant, no samples will be taken from that quadrant. If only one tooth is present in a quadrant, then only 2 samples will be taken.

3. Gingival Crevicular Fluid (GCF) Sampling Sequence

Gingival crevicular fluid is collected and placed into liquid nitrogen for storage prior to mediator assay by radioimmunoassay or ELISA. Four sites in each quadrant will be sampled to provide enough GCF samples for analyses of four mediators per participant. A total of 16 GCF samples are collected per participant using periopaper (10-30 see) and recording the volume with the Periotron 6000. 16 samples will be collected - four per foil strip, four strips - one into each of four vials.

4. Records

The computer screen displays the 16 sample sites to be used and those sites are identified by the computer. The QTS sites are recorded on the Sample Requisition Form. After each sample is read in the Periotron, that reading must be recorded for the appropriate QTS on the requisition form After all 16 of the Periotron readings have been recorded on the form, the readings are then transferred to the computer screen. Be sure to double check that the number on the vial matches that on the sample requisition form. All GCF vials must be transferred to liquid nitrogen tank for storage at the end of the day.

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	GCF		_
Sample 1 Sample 2 Sample 3 Sample 4 Sample 5 Sample 6 Sample 7 Sample 8 Sample 9 Sample 10 Sample 11 Sample 12 Sample 13 Sample 14 Sample 15 Sample 15		Scire Scire Science Sc	

Patient Dental Sample Acquisition	Bar Code:	
		,,, ,,
	PATIENT INFORMATION SECTION	
PRINCIPAL INVESTIGATORS	PATIENT INFORMATION	
Jim Beck, PhD	Initials:	22
Steven Offenbacher, DDS, PhD University of North Carolina	ID#:	
Dental Research Center CB #7455, Rm 222 DRC	COLLECTION INFORMATION	
Chapel Hill, NC 27599-7455	Collection Date: month day year	
Protocol: DARIC	Collection Time: use international notation	•
Tradeson MC	SAUTE STATE	
Geographic Site: Jackson, MS	(check one) GCF/Plaque: 9:30am = 0930 Serum 2:15pm = 1415	is:

SAMPLE SITE (QTS)	PERIOTRON READING	ACCESSION NUMBER	VIAL NUMBER	Comments
		AR -J101	101	
		AR -J102	Red	
		AR -J103	Тар	
		AR -J104	Tube	
		AR -J105	105	
		AR -J106	Green	
		AR -J107	Тор	
		AR -J108	Tube	
		AR -J109	109	
		AR -J110	White	
		AR -J 111	Тор	
		AR -J112	Tube	
		AR -J113		
		AR -J 114		
		AR -J 115	Top	
		AR -J116	Tube	
	Plaque	AR -J217	217	
	Plaque	AR -J218	218	
	Plaque	AR -J219	219	
	Plaque	AR -J220	220	
	Serum	AR -J321	321	
Block W	Serum	AR -J322	322	
Sin Conten	Serum	AR -J 323	323	
	Serum	AR -J324	324	

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5. Daily Sample Storage and Paperwork

After each participant has been seen the GCF samples should be transferred from the Dewar flask into the liquid nitrogen storage tank. There will be a liquid nitrogen storage tank login and logout sheet for each tank at each center. Remove the four vials from the Dewar with tongs and place into a single aluminum cane. Each vial should snap into place onto the cane and be retained tightly, otherwise they can become loose within the liquid nitrogen tank. Wear gloves when handling these samples or transferring anything into or out of liquid nitrogen. Place the cane into the ladle style basket and return to the liquid nitrogen. Always make sure the liquid nitrogen tank is kept at least 3/4 full. This is best achieved by marking 2 days a month on the calendar and always refill the tank every 2 weeks on those days. When the participant samples are placed into the liquid nitrogen tank file the copy of the participant requisition form into a notebook and place the original into a shipping folder. This shipping folder will accumulate participant requisition forms for 2 weeks and then will be mailed along with the shipment of participant vials to serve as a packing slip.

The plaque samples may be stored at room temperature also using a 9x9 divider box. Each box holds enough vials for 18 participants, therefore there should be about three boxes each 2 weeks for plaque ready for shipment. The vials are pre-labeled. but, you need to complete the plaque login sheets (See example on next page).

Storage and Shipping Form for Plaque and Gingival Crevicular Fluid

Participant	Participant	Date	Date	Comments Reasons for
ID	Initials	Stored	Shipped	missing vials, etc.

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6. Quick Reference sheet for Crevicular Fluid Collection

- 1. Have operatory prepared as described previously in the Preparation Section. Have vials set up in rows within the rack such that there are four vials in each of three rows. The first row will be for the GCF samples, the second row for the plaque and the third row for the serum.
- 2. Site to be sampled is identified from the data entry screen. The 16 QTS numbers are recorded on to the Sample Requisition Form.
- 3. Site is isolated and dried. Periopaper is placed into site until visibly dampened.
- 4. Examiner places periopaper into Periotron and closes the sensor on it.
- 5. Examiner returns to step 2) to sample the next site
- 6. Assistant records the final reading on the Periotron on the Sample Requisition Form, removes the periopaper and places it on the foil strip.
- 7. Assistant folds foil over the periopaper at least twice using cotton pliers.
- 8. After every fourth periopaper, the entire foil strip is folded at ends and placed in a cryovial. The number on the cryovial is checked with the appropriate accession number in sequence from the Sample Requisition Form. The cryovial is stored chairside in the flask of liquid nitrogen.
- 9. Assistant returns to step 6) until sixteenth strip is completed.
- 10. Transfer the Periotron readings from the form to the data entry screen according to site number. Place GCF vials in larger liquid nitrogen storage tank.

7.2.1.7 Microbial sampling and analysis of plaque samples

1. Preparation

For supplies, each site will be provided with four plaque sampling vials that are prelabeled, color coded and in the participant sample kit. Each tube contains $100~\mu L$ of sterile 1 x TE buffer. These vials are now stable for several years if the caps are snug. To tighten caps, screw until just barely tight. DO NOT OVER-TIGHTEN.

2. Plaque Sampling

Plaque samples are obtained from the mesial surface of all four first molars using a sterile curette. These samples are each placed in a separate tube for a total of four samples. The four areas to be sampled will be the mesial buccal of all four first molars. If this tooth is missing go to the nearest most posterior adjacent tooth. The site is isolated with a cotton roll and removed of gross supragingival plaque or debris if present and gently dried with sterile gauze or air stream. GCF's should be taken prior to plaque sampling. Plaque samples will be taken by placing a sterile curette to the base of each pocket and, with a single stroke, pressing against the tooth at the depth of the pocket, removing a sample for transfer to the storage buffer. Do not attempt to sample the grossly adherent plaque which appears supragingivally. After collecting one plaque sample, the tip is wiped with an alcohol gauze before taking the next sample. The plaque sample will be placed into the tube containing 0.1 mL sterile TE buffer (pre-made in the Participant Kit provided). Place the tip of the curette into the TE buffer, and twirl the curette between your fingers to remove plaque. If a particularly heavy deposit adheres to the curette, it may be removed by scrapping onto the upper lip of the tube, and then pushing the sample down into the buffer. However, in general, sufficient bacteria will be transferred to the buffer for DNA analysis, even if not visible by eye. This procedure is repeated for the remaining three molar sites.

Following sample collection, 0.1 mL of 0.5 M NaOH (sterile) will be added using the plunger-style dispenser and mixed well by closing the lid tightly and shaking. At the beginning of each day the plunger pump is primed by pumping solution into the sink twice. Check the prelabeled vial to assure that the appropriate accession number matches with the sample requisition form. Samples are stored at room temperature until a sufficient quantity has been obtained to be shipped. Storage may be at room temperature, refrigerator or freezer temperature, as convenient, since they are quite stable (see Jurassic Park).

When plaque samples have been collected and stored, enter a "y" in the designated box on the computer screen in order to move to the next screen.

3. Quick Reference Sheet for Plaque Sample Collection

- 1. Have operatory prepared as described previously and vials in 3x4 rows.
- 2. The sequence of sites to be sampled are as follows: Four samples (mesial of each first molar) in four separate tubes. Use a wiped end of a curette for each site sampled. Adjacent, most posterior tooth may be substituted if first molars are not present.
- 3. Areas to be sampled are cleared of gross supragingival plaque and dried with gauze.
- 4. Obtain the sample by placing the curette at the base of the pocket and removing the sample with a single stroke.
- 5. Place the curette end into the tube (pre-prepared and provided in the Participant Kit). Place below the buffer level and rotate gently.
- 6. Recap tube and repeat with the next sample.
- 7. The pre-labeled tube number is checked against the Sample Requisition Form.
- 8. Sodium hydroxide buffer placed in each vial using pump dispenser, capped shaken and stored.

7.2.1.8 BANA plaque sample collection

BANA plaque samples should be taken after GCF fluid and after plaque sampling. Plaque samples are obtained from the disto-buccal surface of all four first molars using a sterile curette. If tooth is missing go to the nearest-most posterior adjacent tooth. Follow the procedures listed below:

- 1. The site is isolated with cotton rolls.
- 2. Remove a BANA test strip from the bottle. Record the desired tooth and site information on the BANA test form.
- 3. Remove supra-gingival plaque prior to sampling. Then remove the subgingival plaque specimens using a curette and apply onto the raised reagent matrix affixed to the lower portion of the test strip.

- 4. Before taking another specimen, wipe the curette on a clean piece of cotton or other suitable wipe to prevent carry-over of plaque.
- 5. After all sites have been sampled, moisten the upper test matrix with distilled water using cotton rolls (do not use tap water)

ALWAYS REMEMBER THAT THE BANA TEST IS LIGHT SENSITIVE, SO ALWAYS COVER THE TEST AFTER REMOVAL FROM THE BOTTLE IF PLANNING TO LEAVE IT OUT OF THE BOTTLE FOR A LONG TIME.

- 6. Fold the BANA strip at the perforation mark so that the lower and upper test matrix meet with each other. Set the incubator to the setting 2 (blue color).
- 7. Place the BANA test strip into the slot of the incubator. The incubator will be operating when the indicator light comes on, and when the BANA strip incubation is complete the indicator light goes off and the bell rings.
- 8. Separate the lower portion of the test strip at the perforation, and discard it.
- 9. Read the BANA test results on the upper buff-colored reagent matrix according to the reagent test card posted on the wall that was provided with each dispensing bottle.

Negative	Weak Positive	Positive
No blue color observable	Small, faint, traces of blue	Distinct patches of blue
on a pale red-brown	coloration on a pale red- somewhat larger and	
background	brown background	darker than weak positive
		reactions on a pale red-
		brown background

10. Record the BANA test results on the BANA test results form:

Tooth number	Tooth site	Negative	Weak Positive	Positive
Tooth number	Tooth site	Negative	Weak Positive	Positive
Tooth number	Tooth site	Negative	Weak Positive	Positive
Tooth number	Tooth site	Negative	Weak Positive	Positive

7.2.1.9 Probing depth, cemento-enamel junction (CEJ), and bleeding on probing

Probing depth is measured first and recorded on the computer screen for the site. For the same site, the CEJ measurement is made and then the cursor moves to the next site. The measurements start in Quadrant 1, tooth 8 and move from sites 3 (distobuccal) to 1 (mesiobuccal) on each tooth. At the end of quadrant 1, bleeding for the sites just probed is recorded. Measures then move to Quadrant 2, tooth 1, and move from sites 1 (mesiobuccal) to 3 (distobuccal). Bleeding for the sites just probed in Quadrant 2 are recorded. Lingual sites for Quadrant 2, teeth 8 to 1 are then measured for sites 4 (distolingual) to 6 (mesiolingual). Bleeding is then recorded for sites just measured. Quadrant 1, teeth 1 to 8, sites 6 (mesiolingual) to 4 (distolingual) are then measured and bleeding recorded. The same procedure is then repeated for Quadrants 3 and 4. The cursor on the screen moves in the appropriate sequence.

Examination Sequence

Quadrant	Teeth	Sites	
1	8 to 1	Db to Mb	Record BOP
2	1 to 8	Mb to Db	Record BOP
2	8 to 1	Dl to MI	Record BOP
1	1 to 8	Ml to DI	Record BOP
3	8 to 1	Db to Mb	Record BOP
4	1 to 8	Mb to Db	Record BOP
4	8 to 1	Dl to ND	Record BOP
3	1 to 8	Ml to Dl	Record BOP

Probing Depth (PD): Periodontal pocket depth is determined with a UNC-15 periodontal probe at six sites per tooth rounded to the next lower whole mm. The probing depth reading is recorded on the computer screen labeled PD for each tooth.

Cemento-enamel Junction (CEJ): CEJ levels are measured with a periodontal probe at six sites per tooth. The distance from the CEJ to the gingival margin is measured and recorded in millimeters rounded to the next lower mm. Millimeters of recession are recorded as negative numbers, otherwise the number is positive.

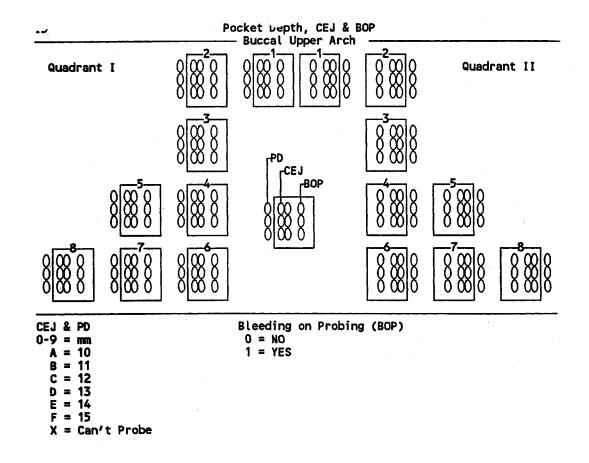
Bleeding on Probing (BOP) - Bleeding on probing is assessed after probing each quadrant on the buccal (surfaces 1-3) and on the lingual surfaces (surfaces 4-6). A dichotomous scoring system is used at six sites per tooth using one (1) and zero (0) for presence or absence, respectively.

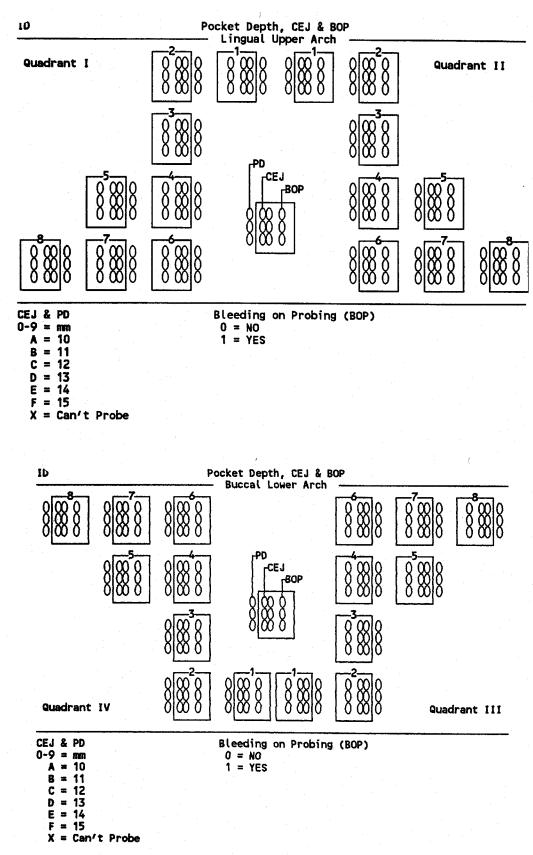
0 = absence of bleeding

1 = bleeding present

CONVENTIONS FOR SCORING PROBING DEPTH AND CEI MEASURES

- If there is a crown and you can see the CEJ, use the CEJ, if not use the crown margin.
- If the deepest probing depth is on the line angle, record it as either facial or lingual, whichever is appropriate.
- Always round down, even if it results in a "10" score
- When reading the probe, if a mm line can be seen, round down to the previous mm score.





8. Shipping instructions

8.1 Plaque and gingival crevicular fluid samples (if obtained)

Samples should be shipped to Dr. Offenbacher on dry ice every 2 weeks. Shipments cannot be made on Friday, as our laboratory has no Saturday delivery. Shipping dates will be pre-assigned at each center, as determined to be mutually convenient dates. Please notify Frances Smith in Dr. Offenbacher's laboratory when a scheduled shipment has been missed or any problem arises by calling (919) 962-7081. If a shipment does not arrive, it can be traced before the dry ice evaporates. Ship Federal Express Overnight Priority Airmail in a thermal insulated container with at least 5-7 pounds of dry ice. Vials should be taken from liquid nitrogen storage, essentially emptying the tank every 2 weeks, and placed into zip-lock baggies, four vials/patient/baggie. Make sure the bags are well-dispersed in the shipping box with the dry ice to keep samples from thawing. Do not touch vials once they are out of liquid nitrogen with your gloves for extended periods of time and do not attempt to open vials. As the vials warm slightly they will release nitrogen into the air, but the nitrogen atmosphere will be retained in the vial with the GCF strip which prevents sample oxidation. Once the GCF samples are packed, the serum samples are placed into the shipping container. The plaque samples are also included in the shipment. All samples need to be logged out as having been shipped using the Storage and Shipping Form (See p. 26). Once samples are received in Dr. Offenbacher's laboratory, they are logged in and placed into liquid nitrogen or freezer for storage.

8.2 Computer data

Data collected from the clinical exam by voice entry is to be shipped from each study center every two weeks. The data entry system will print a two copies of the shipping report. One copy will be kept at the study center the second shipped with the disk. Ship the disk to:

Kevin Moss Room 377 Brauer Hall School of Dentistry University of North Carolina Chapel Hill, NC 27599-7450 Data collected on Periodontal Examination: Backup for Voice Recognition forms should be copied for data entry. The original should be kept in the chart. The copy should be sent to:

Dr. Robert Weyant, Division of Pediatric and Developmental Dental Sciences School of Dental Medicine University of Pittsburgh 3501 Terrace Street Pittsburgh, PA 15261

9. Procedures for performing the measurement at home (if applicable)

Not applicable.

10. Alert values/Follow-up/Reporting to participants

<u>Alerts:</u> There are two urgent findings that should be reported to the clinic coordinator and reviewed by the investigator. These are:

- Suspicious oral soft tissue lesions (possible cancer)
- Acute infection of the teeth or soft tissue

The participant will be told to see a dentist within a week. A copy of the alert and letter will be sent to the investigator.

10.1 Instructions: Participant Summary and Recommendations Form

At the end of the periodontal examination, the Oral Health Examination Report (Appendix 4) will be completed by the examiner.

Make two copies of the form. When the first copy is done, write in the participant's name, and review the recommendations with them. The participant may then move on to the next station. The first copy goes with the participant. Write the participant's name on the other copy. One copy is sent to the participant's doctor/dentist (if authorized by the participant) and the other copy is placed in the record. The report is also reviewed during the exit interview.

11. Quality assurance

11.1 Training requirements

The dental examiner should be a licensed dental hygienist. The examiner's training can be done at the School of Dentistry at the University of North Carolina or by Dr. Robert Weyant.

11.2 Certification requirements

Clinical experience with periodontal assessment is required. In addition, training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Compare measurements with those made by experienced dental hygienist or dentist (Goal: 90% of measurements should be within 1 mm of expert)
- Discuss problems and questions with local expert or QC officer

11.3 Quality Assurance Checklist

Individual Participant Exam Checklist

Daily Room Setup (Before First Participant Exam)

lacksquare Room cleaned, organized, and made ready for exams
Review of "participant" list for each days participants (check edentulism status)
lacksquare Vials selected and set-up for first participant
lacksquare Sterile instruments available in room for all scheduled exams
\square Necessary equipment in room for exams (computer, cryovials, etc.)
lacksquare Computer turned on and software setup for first exam
☐ Software voice check completed before first participant arrives
lacksquare Cryovials are labeled with all participants' ID labels
lacksquare Plaque vials are labeled with all participants' ID labels
lacksquare Backup tape recorder and paper forms in room

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☐ Participant name and ID confirmed to be on all data collection material (cryovials, plaque vials, software)
☐ Participant Dental Questionnaire complete (if not – ask participant the remaining questions)
☐ Periodontal Eligibility Assessment form completed properly
☐ Initial Clinical Exam
☐ Soft tissue
☐ Missing teeth
☐ Gingival Crevicular Fluid Collection
☐ Site Selection Correct
\square No pooled saliva at site
\square Periopaper is placed in Periotron quickly
\square Periotron reading is within range (30-180)
\square Periopaper is transferred to aluminum strips with no contamination
\square Foil strips are folded appropriately and placed in 1.5mm cryovials
☐ Cryovials are properly labeled and placed in liquid nitrogen as soon as possible
\square Gloves worn when working with liquid nitrogen
\square Cryovials properly snapped in place in liquid nitrogen
☐ Periodontal Examination
☐ Plaque score
☐ Bleeding on probing recorded
☐ All sites recorded in proper order
Proper technique is used for all measurements

Plaque Samples
☐ Proper site selection
\square Proper sampling technique used
☐ Sample placed correctly into vial
lacksquare Vials properly labeled
☐ Vials properly recapped
☐ Vials placed into cryo-storage.
☐ BANA Plaque Samples
Proper site selection
Proper sampling technique used
☐ Incubator set to correct setting
☐ BANA results read correctly
☐ BANA results recorded correctly
☐ GI Index
All teeth properly scored
☐ Exam procedures completed in proper sequence
Daily Checklist (end of day)
☐ Backup data onto 3 floppy disks
Printout data files for all patients examined that day
☐ Instruments cleaned and packaged for sterilization
☐ Room cleaned and readied for next day
☐ Storage forms for cryovials and plaque checked and all samples logged
☐ Liquid nitrogen levels checked in cryo-storage container
Weekly Checklist (end of week)
☐ Periotron Calibration completed and logged
\square Initial inter-rater calibration exam completed (eventually will move to monthly)
Biweekly Checklist
☐ Data mailed to analysis center at UNC data center on floppy disk.

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Monthly Checklist
☐ Cryovials mailed to analysis center at UNC
☐ Plaque samples mailed to analysis center at UNC
☐ Order liquid nitrogen refills as needed

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11.4 Quality control certification and recalibration protocol

There are three main components to the quality control plan for the periodontal examination: (1) monitoring the number of periodontal exams completed by each hygienist on a monthly basis; (2) recertification procedures and standards; and (3) ongoing quality control procedures.

Minimum volume for examiners

A periodontal examiner must conduct at least 10 periodontal examinations per month to remain "certified" as an examiner. The number of periodontal exams done monthly by each hygienist will be monitored by a monthly review of an examination log book (Appendix 7).

A daily log of all participants examined should be maintained. Checkboxes include:

- ρ Health ABC Staff ID #
- ρ Date of Year 2 Clinic Visit
- p Participant Health ABC Enrollment ID# and acrostic
- ρ Dentate status (edentate or dentate)
- ρ Whether or not the participant was seen by a hygienist
- ρ Participant had oral health screening but was ineligible for perio exam
- ρ Periodontal exam was completed
- ρ (Pittsburgh only): plaque/BANA/GCF collection

Log books will be reviewed by the Clinic Coordinator at the field center and faxed to Susan Averbach (415-597-9213) at the end of each month, beginning on November 30.

If an examiner fails to maintain the minimum examination rate then a "recertification" process must be completed.

Recertification

A repeat periodontal examination should be completed on one Health ABC participant (or a volunteer). The primary hygienist and the dental hygienist who is being recertified should examine the same participant or volunteer and each fill out a Periodontal Examination: Backup for Voice Recognition form for this exam, and fax it to Susan Averbach at 415-597-9213.

Periodontal examination findings for this participant should exceed 90%

agreement (± 1mm) probing depth.

Ongoing quality control procedures for all dental examiners

As a quality control process we will have all of the examiners complete an exam on a staff volunteer. Ninety percent agreement should be reached by all examiners with their field center standard (Memphis is Gina Warr, Pittsburgh is Vicky Gallo). The first comparative QC exams between the primary hygienist and each other hygienist should be done in one month from now. The primary hygienist and the other hygienist should each fill out a Periodontal Examination: Backup for Voice Recognition form for the exam and fax it to Susan Averbach (415-597-9213). The results will be reviewed at the Coordinating Center and will be reported to the Periodontal QC Working Group who will decide how often the QC procedure will be repeated.

Issues that require discussion/decision should be resolved through the usual Question and Answer process. That is, a Health ABC Question and Answer form should be filled out and faxed to Susan Averbach at the Coordinating Center. She will request an answer to the question, complete the form, and distribute the answer to both field centers so that all examiners will be notified of any interpretations or modifications of the protocol.

APPENDIX 1 Periodontal Exam Eligibility Assessment Form
HABC Enrollment ID # Acrostic Staff ID #
PERIODONTAL EXAM ELIGIBILITY ASSESSMENT
Do you have any of your natural teeth? Yes Don't know Refused
a. How many years ago did you lose your last tooth? If you are unsure, please make your best guess. years Less than 1 year ago b. Do you have any dental implants? Yes No Don't know Refused Not eligible for assessment. Go to Question #11.
Has a dentist or a doctor ever told you that you need to take antibiotics before every dental visit?
Yes Don't know Refused Please explain why: Go to Question #3.
Not eligible for assessment. Go to Question #11.
Has a doctor ever told you that you have any of the following? a. A heart murmur? Yes No Don't know Refused Not eligible for assessment. Go to Question #11.
b. Congenital heart disease? Yes No Don't know Refused (a heart problem you were born with) Not eligible for assessment. Go to Question #11.
C. Rheumatic heart disease? Yes No Don't know Refused
Not eligible for assessment. Go to Question #11. 7100 Page Link # ◆Page 28◆ Version 1.1, 7/30/98

. An infection o	f the lining of th	e heart called	d endocarditis?	
	Yes	No	Don't know	Refused
Not eligible for a	assessment. G	o to Questior	n #11.	
. Mitral valve pr	olapse?			
	Yes	No	Don't know	Refused
Not eligible for a	assessment. G	o to Questior	ı #11.	
Are you taking	prednisone or a	any immunos	uppressive medication	1?
	Yes	No	Don't know	Refused
Not eligible for a	ssessment. G	o to Question	ı # 11.	
Do you have a	cardiac pacema	aker?		
	Yes	No	Don't know	Refused
Not eligible for a	ssessment. Go	to Question	#11.	
Do you have a	surgically impla	nted heart va	alve, shunt, or artificia	joint?
	Yes	No	Don't know	Refused
Not eligible for a	▼ ssessment. Go	to Question	#11.	
Have you had m	najor surgery, ra	idiation, or ch	nemotherapy for canc	er within the last 2 months?
	Yes	No	Don't know	Refused
Not eligible	of for assessmen	it. Go to Que	estion #11.	
Are you on kidne	ey dialysis?			
	Yes	No	Don't know	Refused
Not eligible	for assessmen	t. Go to Que	estion #11.	

9	Have you had a heart, kidney, or other organ transplant? Yes No Don't know Refused
	Not eligible for assessment. Go to Question #11.
0	Did you ever take FenPhen to lose weight? (Examiner Note: If participant says they used another diet pill but they do not remember the name of the pill, check "X" yes.)
	Yes No Don't know Refused
	Not eligible for assessment. Go to Question #11.
Ð	Is the participant eligible for the periodontal assessment?
_	Yes, eligible for the periodontal exam
t a a d a d a d a d a d a d a d a d a d	Eligible for the periodontal exam. Examiner Note: Read the following statement.) This next measurement includes a simple examination of your mouth to see if there are any savities, gum disease, or spaces between your each and gums. We will also collect a little plaque and pick up some fluid from around your teeth. Most people find these procedures quite comfortable. You you have any questions? If you would like us to send your dentist a copy of our dental exam report, please provide us with their name and address. Dentist's Name: Address:
	Bar Code Laber

APPENDIX 2 Definitions and Synonyms of Medical Terms

MEDICAL CONDITION	<u>DEFINITION</u>
CONGENITAL HEART DISEASE	Heart disease which is present since birth and which is diagnosed either at birth or early in a person's life.
RHEUMATIC HEART DISEASE	Damage to the heart valves caused by a strep infection, which can manifest itself from slight heart murmurs to pump failure of the heart.
HEART MURMUR FROM A DEFECT IN THE STRUCTURE OF THE HEART	Heart murmur due to problems of the heart valves or the arteries leaving the heart, (not what are often called "innocent" heart murmurs).
INFECTION OF THE LINING OF THE HEART, CALLED ENDOCARDITIS	No other synonyms available
MITRAL VALVE PROLAPSE	Protrusion of the heart valve, called mitral, which causes some difficulties to the pumping function of the heart.
CARDIAC PACEMAKER	Implanted electrical device used to trigger or regulate the heart beat
HEART/KIDNEY/OTHER ORGAN TRANSPLANT	No other synonyms
SURGICALLY IMPLANTED HEART VALVE, ARTIFICIAL JOINT, STENT OR OTHER BODY PART	A stent is a device placed in an artery during angioplasty to help keep the artery from collapsing after surgery.
PREDNISONE OR OTHER IMMUNOSUPPRESSIVE MEDICATION	If uncertain, have participant ask their doctor before the Health ABC visit.

APPENDIX 3 Dental History

= 4	lealth AB		TAL HISTORY	HABC Enrollment ID	# Acrostic
42.	How wou (Intervie	Id you rate your overall oral is wer Note: Read response of Excellent Good Fair Poor Don't know Refused	nealth (teeth, gums, insi options.)	de of mouth)?	
43.	How ofte	n do you brush your teeth in a Not at all One time Two times Three or more times Don't know Refused	an average day?		
44.	How ofte	n do you use dental floss in a Not at all One time Two times Three or more times Don't know Refused	n average week?		
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APPENDIX 4 Oral Health Examination Report

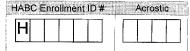
Health ABC	HABC Enrollment ID # Date of Exam H
ORAL F	HEALTH EXAMINATION REPORT
Type of exam: Oral	Health Screening Periodontal (Gum Disease) Screening
Findings: Good	oral health One or more areas are abnormal
	(Examiner Note: Check all that apply.) Soft tissue
	Teeth Probable cavities Loosening
	Gum Disease Mild Severe
Comments:	
Recommendations:	
See your dentist/hygienist	
	Within 1 month
a substitute for the comple seeking dental care, since our evaluation of your den examination by your dentis add to your knowledge of	As soon as possible: within 1 week mination was conducted as part of the Health ABC Study. It is not set examination given to people who go to a dentist/hygienist neither a complete dental history, nor x-rays were taken. Thus, tal condition may not necessarily agree with the results of an st. However, the recommendation of our hygienist is provided to your dental health. The staff of the Health ABC study would like to ank you for participating in this important study.
	Hygienist
	,9.0

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APPENDIX 5 Periodontal Examination: Backup for Voice Recognition

Hea	w		F	ABC E	nrolln	nent	1U#.		Acro	SUC			ate F	orm u	Jomp	leted		<u>S</u>	taff ID	7
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F		· · · · · ·		BAC											TIC	NC				
Examiner N	ote: I	t voi	ce-re	cogni	tion	syste	em is	not	vorki	ng, r	ecore	d dat	a bel	ow.						
ls parti	icipan	t con	nplete	ly ede	ntulo	us?				⁄es		No								
Missi	ng Tee	eth (c	heck a	ıll miss	ing te	eth)														
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	8	7		5 4 Q4	3	2	1			1	2	3	4	Q 3	6	7	8			
Plaqu	ie Sco	ore (0	-3)																	
	8	7	6	5 4 Q1	•	3	2	1			1	2	3	4 Q 2	5	6	7	8		
	8	7	6	5 4 Q4	: :	3	2	1			1	2	3	4 Q 3	5	6	7	8		
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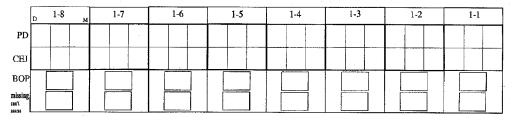




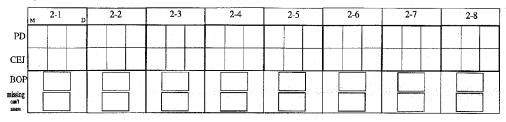
PERIODONTAL EXAMINATION

PD=Probing depth; CEJ=Cemento-enamel junctions; BOP=Bleeding on probing FACIAL

Quadrant 1

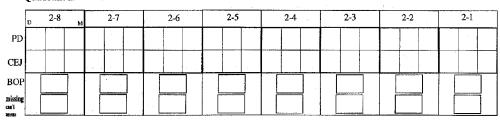


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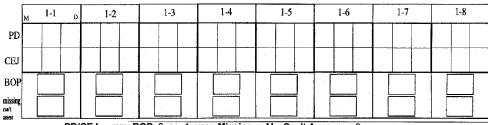


LINGUAL

Quadrant 2

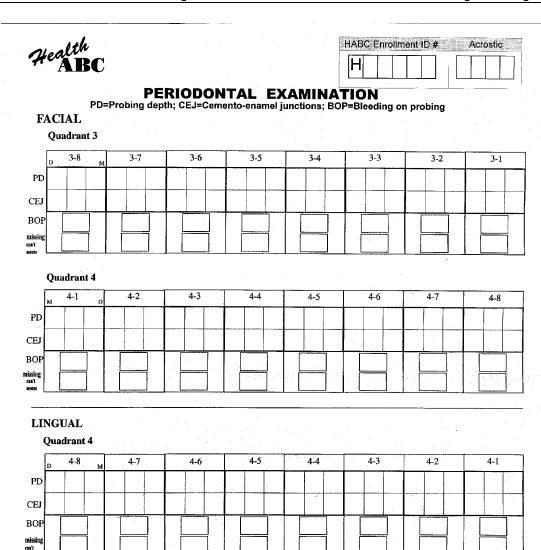


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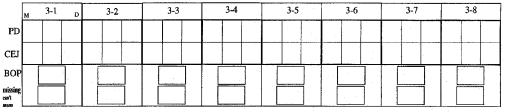


PD/CEJ = mm; BOP: 0=no, 1=yes; Missing = M; Can't Assess = 9 ◆Page 2◆

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Quadrant 3	
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PD/CEJ = mm; BOP: 0=no, 1=yes; Missing = M; Can't Assess = 9

◆Page 3◆

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APPENDIX 6 Dental Examination Addendum (Hard Tissue Findings)

- 0+la	HABC Enrollment ID # Acrostic Date Form Completed	Staff ID#
Health ABC	H	
	BENEAL TWATTHEFT AND ADDRESS.	
	DENTAL EXAMINATION ADDENDUM:	
s (are) there'	HARD TISSUE FINDINGS	

0	Probable caries?	Yes No	
		Number of teeth involved:	
9	Mobility?	Yes No	
		Number of teeth involved:	
6	Root fragment(s)?	Yes No	
		Number of teeth involved:	
A	Furciation?		_

4	Furciation? (Ability to probe between roots of a tooth	Yes	No
		Number of teeth involved:	

APPENDIX 7 Examiner Volume Log for Periodontal Examination

Health ABC	PERIODONT	ITAL EXAMINATION LOG (MEMPHIS)								
HABC Enrollment Acrostic	Date of Year 2 Clinic Visit Month Day Year	Please check all that apply Staff ID # Not Oral Health Perio Perio Comments Seen Screening Screening exam Ineligible edentulous completed								
			Billoms							
			(NIS)							
			elizira							
			(213140)							

Health ABC	PERIODONTAL EXAMINATION LOG (PITTSBURGH) Please check all that apply												
HABC Enrollment	Acrostic	Date of Year 2 Clinic Visit Month Day Year	Staff ID#	Not Seen	Screening	Please c Oral Health Screening edentulous	Perio exam	Plaque	BANA	GCF		omments	
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											######################################	Parameter Contraction	and a second
												Belling Control	
											ti Singangan wa	***************************************	
												Harris Marian Line	
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